

DEPARTMENT OF HEALTH AND HUMAN SERVICES

MEMORANDUM OF CONFERENCE

September 23, 1994

Participants:

Monsanto:

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FDA:

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Subject: Colorado potato beetle-resistant potato.

Keywords: Potato; Colorado potato beetle (insect) resistance; pesticidal protein from *Bacillus thuringiensis* subspecies *tenebrionis* (*B.t.t.* protein); APH(3')II; *kan^r*; Npt II.

This meeting was intended to bring Monsanto's consultation with FDA on the food and feed safety of this product to closure.

Intended Effect, Food/Feed Use

The intended effect of this genetic modification is to render potato (*Solanum tuberosum*) plants resistant to the Colorado potato beetle (CPB), a major pest. Potatoes are primarily used for human food; animal feed use is minor and is limited to occasional localized use.

Mechanism of the Intended Effect

B.t.t. protein is selectively toxic to a narrow spectrum of *Coleopteran* insects. Ingestion of potato tissues expressing *B.t.t.* protein results in inhibition of feeding, disruption of the gut epithelium, and the eventual death of susceptible insects.

Regulatory Considerations

The use of *B.t.t.* protein, a pesticidal substance, is under the Environmental Protection Agency's (EPA's) regulatory purview. In this instance, the APH(3')II/Npt II protein is being used as a plant pesticide inert ingredient. For this reason, this use has been regulated by EPA (see the Federal Register of September 28, 1994 (59 FR 49351)). Based on the above, the focus of this meeting was limited to Monsanto's characterization of the composition and wholesomeness of the seven Russet Burbank CPB-resistant potato varieties they have developed.

Compositional Analysis

Based on the nature of the genetic modification, it was not expected that CPB-resistant potatoes would differ significantly in composition from other potato varieties. To confirm this expectation, Monsanto compared the composition of CPB-resistant potatoes to the composition of the non-transgenic parent line.

Based on their analysis, Monsanto has concluded that the seven varieties of CPB-resistant potatoes they have developed do not reproducibly differ in protein, fat, fiber, ash, carbohydrate, solids, dextrose, sucrose, vitamin C, glycoalkaloid (solanine and chaconine), thiamine, pyridoxine, folic acid, riboflavin, niacin, or nutritive mineral (calcium, copper, iron, iodine, magnesium, phosphorus, potassium, sodium, and zinc) content from the non-transgenic parent variety.

Wholesomeness Studies

Monsanto described the results of a wholesomeness study they carried out in rats. On the basis of their consideration of the results of this study, Monsanto has concluded that there is no significant difference in the wholesomeness of CPB-resistant and control lines of potatoes, as expected from their compositional analysis.

Conclusions

Monsanto has concluded, in essence, that the Colorado potato beetle-resistant potato varieties they have developed are not significantly altered within the meaning of 21 CFR 170.30(f)(2) when compared to potato varieties with a history of safe use. At this time, based on Monsanto's description of its data and analysis, the agency considers Monsanto's consultation on this product to be complete.

F. Owen Fields, Ph.D.

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